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Health Resources & Services Administration

Program Advisory

Use of Zidovudine (ZDV) to Reduce Perinatal HIV Transmission in HRSA-Funded Programs

December 1995

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

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Dear Colleague:

The enclosed document, *Use of Zidovudine (ZDV) To Reduce Perinatal HIV Transmission in HRSA-Funded Programs*, is being made available to all HRSA-funded providers of care and services to women. It provides practical implementation strategies for establishing and maintaining standards of care for pregnant women in the United States. These strategies are based on U.S. Public Health Service (PHS) recommendations for HIV counseling and voluntary testing for pregnant women and for offering the ZDV perinatal regimen to pregnant women infected with HIV. This Program Advisory fully discusses these strategies, principles, recommendations, and options. It is based upon the best currently available scientific information and was developed by a process that included extensive input from providers and consumers through public meetings and a public comment process.

We expect our programs to implement these PHS recommendations. We will work with State and local health departments and providers of health care and services with technical assistance, training, materials, and other resources as they are made available to assist in implementing these recommendations. As a result of these efforts, we anticipate that HRSA will be instrumental in reducing the transmission of HIV from mothers to children, thereby preventing a significant number of cases of pediatric AIDS and in improving the health of women living with HIV and AIDS.

We appreciate your assistance in our HIV efforts and urge you to continue in your cooperation and support.

Yours sincerely,

Ciro V Sumaya

Ciro V. Sumaya, M.D., M.P.H.T.M.
Administrator

Enclosure

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Program Advisory

Use of Zidovudine (ZDV) to Reduce Perinatal HIV Transmission in HRSA-Funded Programs

This advisory is designed to guide the implementation of PHS recommendations for HIV counseling and voluntary HIV testing for pregnant women[1] and for offering the ZDV perinatal regimen to pregnant women with HIV[2] in HRSA-funded programs. It is intended for use by primary care providers including nurses, physicians, social workers, counselors and outreach workers and for program administrators in all HRSA programs. This includes community and migrant health clinics, maternal child health programs, Ryan White programs and other HRSA grantees.

These recommendations (PHS Recommendations for Use of ZDV to Reduce Perinatal Transmission of HIV[2] and for HIV Counseling and Voluntary Testing for Pregnant Women[1]) represent the standard of care for pregnant women and should be followed in all HRSA-funded programs.

HRSA grantees will provide counseling and voluntary HIV testing for all pregnant women and for women considering pregnancy, either on-site or by referral to counseling and testing programs, and will strongly encourage all pregnant women to know their HIV status. Grantees will provide counseling on the availability of the ZDV perinatal regimen for all pregnant women with HIV in culturally, linguistically and age-appropriate language to enable women to make fully informed decisions. Application guidance for HRSA HIV/AIDS programs will require grantees to address planning and reporting activities that assist in implementing these recommendations. Guidelines, strategies and options follow for implementing the ZDV perinatal regimen in HRSA-funded programs.

SUMMARY

Interim results of ACTG 076 in February 1994 showed a significant (two-thirds) reduction in transmission of HIV from mothers to infants. Based on these findings, NIH closed enrollment of the study and the Public Health Service developed recommendations for use of ZDV to reduce perinatal transmission of HIV. These interim results have been confirmed through continued follow-up of mothers and infants enrolled in this trial.*

Benefits and Risks

The ZDV perinatal regimen has been shown to be very effective in reducing maternal-infant transmission of HIV, with minimal short-term effects on women and infants. Because long-term effects are unknown, mothers who choose this option, and their children, should receive follow-up care to monitor for any potential long-term adverse effects.

Community Planning and Participation

Community planning, coordination and education are needed at all levels to implement PHS recommendations. Women with HIV and representatives from programs serving women and families should be an integral part of all local, State and regional planning. HRSA will work closely with grantees and with related agencies in Federal, State and local

*HRSA will make this information available to grantees when results are published.

government to facilitate coordination of planning efforts. HRSA will also work with Ryan White grantees to develop procedures for documenting implementation of the regimen, which will likely be required by the reauthorized CARE Act.

Provider Training and Technical Assistance

Health care workers should receive training in HIV counseling and testing, management of HIV disease, and implementation of the ZDV perinatal regimen. This includes training in cultural competency, clients' diverse educational and linguistic needs, non-coercive decision-making as well as the emotional, practical and support needs of women, adolescents and families. The Public Health Service is currently developing educational materials for clients which are projected to be available in January 1996. HRSA is also developing provider training materials which will be available later in the year. Each HRSA Bureau will use a variety of mechanisms to assist grantees in implementing this advisory.

HIV Counseling and Testing and Informed Decision-Making

All HRSA programs that provide care to pregnant women and women considering pregnancy should provide routine counseling and voluntary testing on-site or by referral. All pregnant women with HIV should receive information on the benefits and potential risks of ZDV use during pregnancy to enable them to make fully informed choices. Information should be provided in clear, culturally, linguistically, and age-appropriate language. Women should be clearly informed that they will continue to receive ongoing care, whether or not they choose to take ZDV. Programs should ensure that women receive appropriate counseling and give written, informed consent (see Appendix D).

Comprehensive Care and Follow-Up

Providers should make the ZDV regimen available to women (and their infants) who choose this option, either on-site or by referral. Implementation requires coordination and strong linkages among primary care, obstetric, hospital/delivery and pediatric health professionals. Agencies should develop written policies and procedures for offering and providing the regimen.

All women and infants receiving the regimen should receive long-term follow-up care. Providers should document infection status and long-term clinical outcomes for both mothers and infants, while observing all laws, regulations and provisions that safeguard the confidentiality of medical records.

Implementation

HRSA will continue to work with grantees to provide technical assistance and guidance in implementing this advisory, and to ensure compliance with the reauthorized CARE Act in meeting the needs of all clients, in particular, women, adolescents and children.

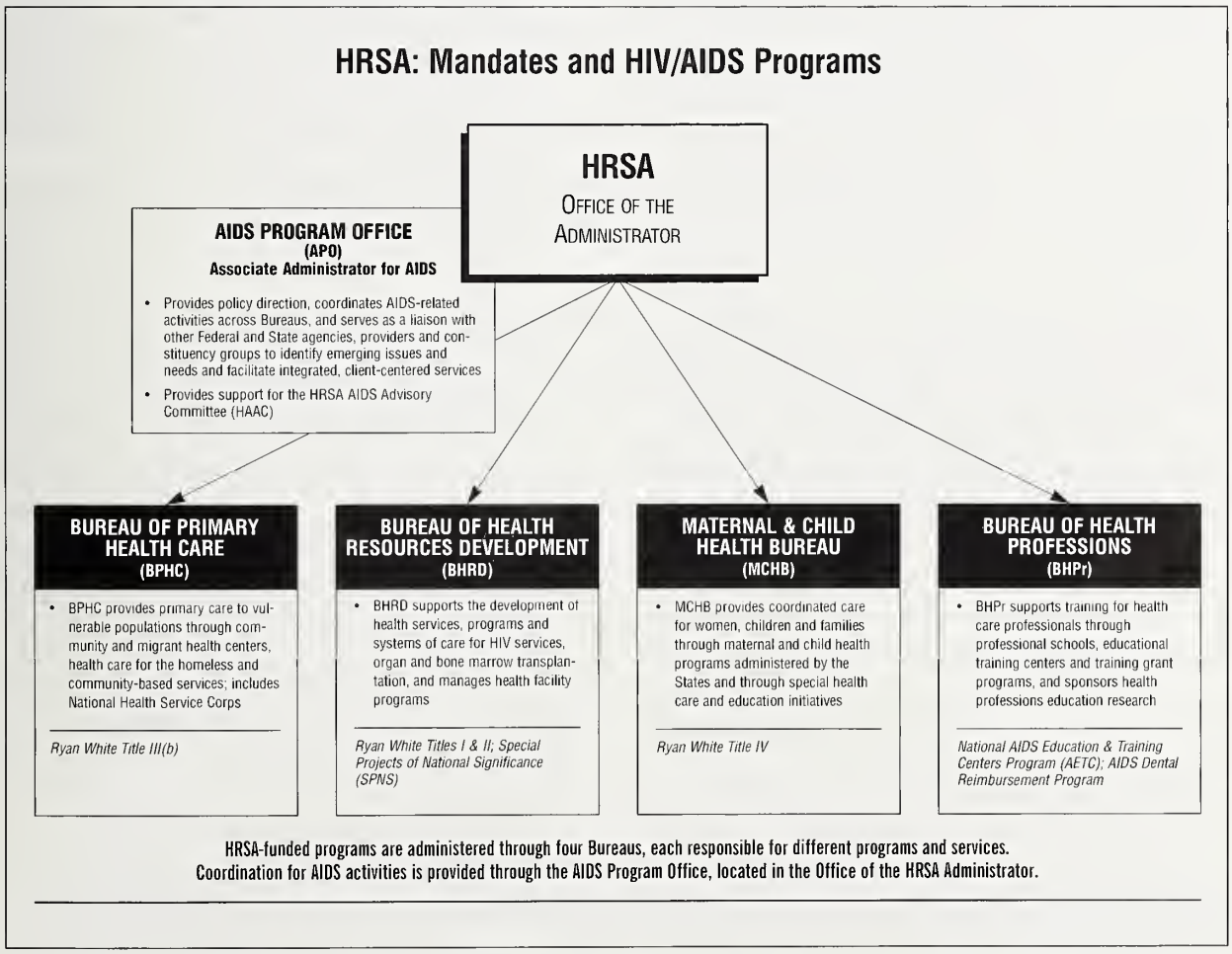
BACKGROUND

In February 1994, the National Institutes of Health (NIH) announced findings of a study sponsored by the Pediatric AIDS Clinical Trials Group (ACTG) which found that a regimen of Zidovudine (ZDV) reduced perinatal transmission of HIV by two-thirds in infants whose mothers met specific eligibility criteria. (Specifics of the trial and its findings are discussed under ACTG 076, page 5.) These findings have direct implications for the growing number of women with HIV disease, for their children, families, and providers, and for the multiple systems that deliver ongoing services and care.

In response to these findings, agencies of the U.S. Public Health Service (PHS) developed recommendations for providing HIV counseling and voluntary testing to pregnant women[1] (see Appendix A) and for offering the ZDV perinatal regimen to pregnant women with HIV[2] (see Appendix B).

This program advisory was developed to assist providers in making the ZDV regimen available through the thousands of health service programs supported by the Health Resources and Services Administration (HRSA), the PHS agency responsible for facilitating access to quality care for underserved and vulnerable populations, and for promoting professional training related to primary care (see diagram on the following page).

This advisory provides background information and specific strategies and options for implementing PHS recommendations in all HRSA-funded programs. This includes: information on the epidemiology of HIV in women and children, results of ACTG 076, PHS guidelines, and principles and strategies for incorporating the regimen into routine management and care of women at risk for and infected with HIV.



These strategies and this advisory were developed through extensive consultation with HRSA constituents, including women with HIV, providers, representatives of national organizations, and program administrators at local, State and Federal levels, based on public meetings held during 1994.* A draft advisory was distributed for public review and comment in June 1995; all comments were carefully considered in preparing the final version.

In convening the public meetings, HRSA had the following goals:

- To examine women's HIV-related care and support needs and explore strategies for increasing women's awareness of their HIV status, of ZDV as an option for reducing transmission of perinatal HIV, and of the regimen's benefits and potential risks;
- To discuss the clinical, legal, ethical, and financial issues related to implementing PHS recommendations in HRSA-funded programs; and
- To obtain guidance from constituents in developing practical, comprehensive strategies to provide the ZDV perinatal regimen (within a comprehensive community-based system of care) as an option for women with HIV, through this program advisory and with ongoing consultation with consumers and providers.

Guiding principles developed by constituents during HRSA's initial public meeting in May 1994 formed the basis for subsequent activities. The principles were shared with participants at the joint NIH and CDC workshop in June 1994 where PHS recommendations for the perinatal regimen were developed. The principles provided guidance in planning HRSA's follow-up meeting in September 1994 to discuss issues and concerns related to implementing the regimen in key program areas, including: community planning, provider training, client education and decision making, counseling and testing, clinical management during pregnancy, and long-term care and follow-up needs of women and children. They were endorsed by HRSA's Administrator as key principles in a letter sent to all HRSA-funded programs in January 1995. That letter urged providers to adopt PHS recommendations as the standard of care in implementing the ZDV perinatal regimen. Moreover, these principles provide the framework for program strategies and implementation discussed in this advisory.

In defining implementation principles and strategies for its providers, HRSA is attempting to respond to the challenge of making the ZDV regimen a widely available option, while seeking to promote counseling and care that respect the realities of women's lives — including their need for informed decision-making and the right to choose. These recommendations should be implemented in all settings where women routinely receive care. In making this option available, providers should acknowledge that pregnancy is a time-limited event and not all women become pregnant; quality care should be available to women at all life stages.

*HRSA Focus Group Meeting of Women with HIV, May 24, 1994; HRSA Working Group on Prevention of Perinatal Transmission of HIV, May 25, 1994; HRSA Meeting – ZDV Therapy for Reduction of Perinatal HIV Transmission: Implications for Care, September 19-20, 1994.

HIV/AIDS IN WOMEN & CHILDREN

AIDS has continued to increase steadily among women, accounting for a total of 68,021 reported cases as of June 1995. Of these, more than three-quarters are African-American and Hispanic; approximately half were infected through injecting drug use and one-third through heterosexual contact. As the epidemic has spread to smaller cities and rural areas, the proportion of cases among women has also continued to rise. Women currently account for 14 percent of all cumulative reported cases of AIDS, up from 10.4 percent in 1990. Of new cases reported during 1994, 18 percent were among adult and adolescent women, with an increasing proportion infected through heterosexual transmission.

AIDS has become a major cause of death among women and children, representing the fourth leading cause of death among women, ages 25-44, and the seventh leading cause of death among children, ages 1-4. In high incidence States and among African-American and Hispanic women, these rates are even higher.

Each year in the U.S., approximately 7,000 infants are born to women with HIV. Of these, 1,000 to 2,000 infants are estimated to be HIV-infected based on a perinatal transmission rate of 15-30 percent. Since routine screening of blood and blood products has essentially eliminated this route of transmission in children, virtually all new infections in infants and children are transmitted perinatally.

HIV is transmitted from mother to infant during pregnancy, labor and delivery or postpartum through breast feeding. According to current estimates, approximately 65-70 percent are infected at or around the time of delivery, with the remainder during pregnancy. In the U.S., only a small percentage of infants — approximately 1 percent — are infected through breast feeding. Several factors are associated with increased risk for maternal-infant transmission in pregnant women, including advanced HIV disease, low CD4+T-cell levels, high viral load (high level of virus in the blood), premature rupture of membranes and premature delivery.

A follow-up study of HIV/AIDS cases reported to the CDC found that 90 percent of women with HIV/AIDS had been pregnant at some time and 75-80 percent reported having given birth.[3] Three-quarters had their first pregnancy by age 25 while half were less than 20 years of age at the time of their first pregnancy. These findings underscore the extent of teen pregnancy in women at risk for HIV infection and the need for awareness among providers of adolescents' risk for HIV. Awareness of HIV status for all pregnant women and women considering pregnancy and early diagnosis prior to and at initial stages of pregnancy are essential for appropriate prevention and optimal care for women and their children.

ACTG 076

In 1991, NIH initiated a clinical trial — ACTG 076 — to determine whether Zidovudine (ZDV) could reduce perinatal transmission of HIV. This study is one of many clinical trials which continue to evaluate treatments for adults and children affected with HIV disease.

Participation was limited to women between 14-34 weeks of pregnancy who had: 1) received no prior treatment with ZDV during their current pregnancy; 2) no clinical indications for antiretroviral therapy prior to pregnancy; and 3) a CD4+T-cell count of greater than 200/mL at the time of enrollment in the study. Women were randomly selected to receive either ZDV or a placebo which was taken orally for the remainder of their pregnancies, administered intravenously during labor and given orally to newborns during their first 6 weeks of life, beginning within 24 hours after birth. A total of 477 women and their infants (421 babies were born during the study period) were enrolled as of December 1993. Participants reflected the ethnic and racial make-up of women with HIV in the U.S.; 79 percent were either African-American or Hispanic.

NIH announced interim results of the study on February 21, 1994. Preliminary findings on 363 infants showed that HIV transmission was reduced by two-thirds, from 25.5 percent in infants whose mothers were assigned to the placebo group to 8.3 percent in infants receiving

DOSAGES
ZDV PERINATAL REGIMEN

DURING PREGNANCY:
100mg orally 5x/day

DURING LABOR AND DELIVERY:
Loading dose: 2mg/kg IV
Followed by continuous infusion of 1mg/kg

INFANTS: FIRST 6 WEEKS:
2mg/kg orally every 6 hours for 6 weeks

ZDV. Therapy was well tolerated by both mothers and infants with no significant short-term effects other than reversible mild anemia in some infants who received ZDV. Based on these findings, NIH accepted recommendations from an independent advisory board to close enrollment in the study and to offer ZDV therapy to mothers who received the placebo and had not yet delivered, and to their infants who were less than 6 weeks of age. The board stressed the importance of long-term follow-up to monitor for the possible development of adverse reactions at a later time.

Women were followed for 6 months after delivery. Those who could benefit clinically from on-going ZDV therapy were offered access to the drug. A follow-up study will monitor effects on women's health for 3 years after delivery. Infants will be followed until 18 months to confirm their HIV status. The study will end in January 1996, when all infants will have reached 18 months of age. All infants in the study are eligible to participate in a follow-up study (until age 21) to identify any long-term effects of ZDV (see box on page 7).

Limitations

Although ACTG 076 has shown that a regimen of ZDV can substantially reduce perinatal transmission of HIV in infants born to women whose immune systems are relatively intact, there are several important limitations:

- Because researchers do not know when infection actually occurs, ACTG 076 was designed to interrupt perinatal transmission at three time points: during pregnancy, during labor and delivery, and in the infant (during the first 6 weeks of life). As a result, the study is unable to show whether a shorter regimen (for example, providing ZDV during delivery alone) would be as effective in reducing transmission;
- Women with advanced HIV disease or previous antiretroviral therapy were not included in the study; nor were women who participated in the study tested for viral resistance to ZDV. As a result, the study provides no information on the regimen's effectiveness in reducing perinatal transmission under these conditions;
- The study provides no information on the long-term effects of ZDV on infected or uninfected infants;
- The study provides no information on the effectiveness of ZDV in treating postpartum women at later stages of HIV disease (following brief treatment during pregnancy);
- The study did not include women during the first trimester of pregnancy, so information is not available on the risk of taking ZDV during the first 3 months;
- Although the regimen can significantly reduce HIV transmission, ZDV does not prevent infection in all infants; one out of 12 babies born to mothers receiving ZDV who participated in the study still became infected; and
- Although ACTG 076 did not result in serious negative short-term effects, it is unclear if this will change when the regimen is more widely implemented with a larger number of women and children.

ACTG 076 was carried out in controlled research settings with access to a full range of medical and support services and better treatment adherence than generally occurs in routine care settings; this may result in more effective outcomes for women and infants. When

the regimen is implemented in community settings, the rate of perinatal HIV transmission may be different since community providers are more likely to treat women who do not receive a full course of therapy, including women at later stages of pregnancy or those who are already in labor. Because many women do not know they are infected with HIV and many do not receive prenatal or preventive care, community-based providers are also more likely to implement the regimen with women at more advanced stages of HIV disease.

Nevertheless, several observational studies conducted in the U.S. in community settings have shown that the ZDV regimen is effective in women at different stages of HIV disease. [4,5,6]

RELATED RESEARCH

Some of the questions raised by ACTG 076 will be addressed when results of several other clinical trials are ultimately available. These include follow-up studies to assess the long-term effects of ACTG 076 on both women and their children. In the interim, however, long-term follow-up of mothers and infants in primary care settings is essential to monitor for potential negative health outcomes, such as carcinogenicity teratogenicity (birth defects), and neuro-behavioral effects, which have been known to occur as a result of *in utero* exposure to other drugs. To date, no increased incidence of birth defects has been found in infants whose mothers received antiretroviral drugs (including ZDV) during pregnancy, based on data collected by the Antiretroviral Pregnancy Registry.*

Consumer education activities should include information on related research to help women and family members understand the incremental nature of clinical trials and assist them in interpreting results. Understanding the differences between these studies can also help address questions that may arise when results of other trials are publicized. For example, two pediatric studies involving use of ZDV — ACTG 152 (a treatment study) and ACTG 076 (a prevention study) — are sometimes confused. The results cannot be compared, however, since the design and purpose of both studies are very different. HRSA will provide grantees with updates on relevant research to include in provider training and consumer education activities as more information becomes available. This includes results of subsequent observational studies of the ZDV perinatal regimen in diverse populations of women, which show similar findings but had not been released at the time this advisory was written.**

FOLLOW-UP STUDIES

ACTG 219 is a long-term follow-up study of infants and children who participated in ACTG perinatal and treatment studies — including ACTG 076 — to monitor for any long-term effects. The study will follow infants and children until 21 years of age.

ACTG 288 is a follow-up study of women enrolled in ACTG 076 (who received either ZDV or placebo) to evaluate health outcomes, such as disease progression, quality of life and response to antiviral therapy. Women will be followed for 3 years after delivery, with the study expected to end in July 1997.

PROGRAM STRATEGIES AND IMPLEMENTATION

Implementing PHS recommendations for offering the ZDV perinatal regimen through HRSA-funded programs has the potential to prevent illness and death in many infants and children. However, effective implementation requires collaboration between providers and communities, broad availability of HIV counseling and testing services, well-coordinated long-term comprehensive care and close consultation between providers and women with HIV who will ultimately decide whether or not to choose this regimen. It also requires providers to adhere to ethical standards, in partnership with women with HIV and affected communities, and in accordance with applicable local

*The confidential Registry was established in January 1989 to follow infants exposed *in utero* to antiretroviral drugs, for development of potential birth defects. The Registry is managed by several pharmaceutical companies and includes an advisory committee with representatives from the CDC, NIH, and other obstetricians.

**HRSA will make this information available to grantees when results are published.

and State laws and regulations. In implementing these recommendations, HRSA will work closely with State and local governments to promote maximum flexibility, support local control and enhance existing initiatives.

The multiple challenges of making this regimen available nationally have been addressed in HRSA-sponsored meetings and through ongoing consultation with constituents, consumers and providers. These discussions have resulted in the development of this advisory, including the guiding principles and implementation strategies presented in four sections of this document. These sections are not intended to stand alone but rather constitute a programmatic whole; many of the issues raised cut across all four areas and many are directed to an ideal of comprehensive, coordinated care that may be difficult to achieve, given the realities of limited resources and competing needs.

Implementing this advisory takes place within systems of care that present long-standing barriers for women, racial and ethnic minorities, the poor and persons at risk for and infected with HIV. Poor coordination between HIV-related services, other categorical programs and mainstream health service delivery has further isolated women at risk for and infected with HIV who, before treatment options can even be made available, must first be identified. Successful implementation of this regimen and related comprehensive services, however, will improve access and services for all women and men by enhancing ongoing planning between multiple service delivery systems, and by increasing coordination and collaboration between diverse agencies and groups. The coordination and linkages required to implement this regimen for pregnant women with HIV are, essentially, no different than the coordination required to deliver comprehensive services to any other population with HIV or to persons with other health conditions that require ongoing care and support.

Successfully overcoming these barriers requires coordinated, systematic planning involving women with HIV; coordination among a range of providers to achieve an accessible, responsive continuum of care for women and their families; and appropriate training and technical assistance for providers and programs.

Implementing this advisory will also require ongoing collaboration and interaction with HRSA and other Federal agencies, local planning, access to technical assistance and training, and information on model programs and educational materials. Prior to distributing this advisory, HRSA prepared an internal agency and Bureau plan for coordinating implementation of the ZDV perinatal regimen in HRSA-funded programs (see Appendix C for a description of primary coordination strategies). Each Bureau has identified ongoing mechanisms for providing information to grantees and to assist them in defining technical assistance (TA) needs related to this advisory. HRSA and its Bureaus will continue to collaborate with appropriate State and Federal agencies, national organizations, professional associations and constituents to facilitate coordination and information sharing. As additional clinical and related information becomes available, HRSA will make it available to grantees while continuing to solicit feedback on implementation. HRSA will also work with Ryan White grantees to develop procedures for documenting implementation of the regimen, which will likely be required by the reauthorized CARE Act.

Principles and related issues follow in each of four implementation areas.

COMMUNITY PARTICIPATION & PLANNING SYSTEMS OF CARE

Principles:

- Women with HIV should serve as an essential resource for policy development, planning, community outreach, and educational activities.
- Community planning, coordination and education are needed at all levels to implement PHS recommendations for HIV counseling and voluntary testing for pregnant women and offering the ZDV perinatal regimen.

Planning priorities include:

- developing appropriate services (e.g., primary care linked to counseling and testing sites, specialty care, case management and support services);
- providing follow-up care for women and children; and
- coordinating care across a variety of programs and funding streams (HRSA, CDC, SAMHSA, Medicaid and private third-party insurers). This requires linkages between multiple systems of care including reproductive health services, substance abuse treatment, and mental health services.

- Programs, planning bodies and educational materials should be diverse, family-centered, culturally-competent and community-based.

Issues Related to Implementation

Participation of Key Informants/Gatekeepers

Women neither receive nor request all essential health-related information from medical providers. Much important information related to health and self-care is passed on by key informants within communities, including family members, clergy, community leaders or respected "elders." These gatekeepers should be included as primary participants in educational and outreach activities; their involvement can ensure a program's success. Lack of trust in health care providers coupled with a widespread misperception that ZDV is harmful to minorities (particularly African-Americans) is a significant barrier to making informed choices.

Women and family members are an important resource for increasing community awareness of available services and treatment options. As community members with established roots and personal networks within their communities, they can serve as a bridge between providers and consumers by explaining the benefits and potential risks of treatment, interpreting confusing medical jargon and helping providers understand the needs and concerns of their patients. Since women with HIV are more likely to be trusted by other community members, their involvement with a specific program can encourage and increase community participation.

Representation

Historically, categorical funding and inadequate planning resources have contributed to fragmented or parallel services, particularly for women whose care has generally been organized around reproductive health needs. As a result of the Ryan White CARE Act and CDC HIV prevention community planning, comprehensive planning efforts have begun to improve coordination and access to care for some women with HIV.

However, additional planning efforts are needed that include the full participation of women, youth and family members in developing policies, services, educational materials and outreach strategies. Women with HIV and their families have been under-represented within community-based AIDS networks and organized planning groups (e.g., Title I HIV Planning Councils). As a result, their complex needs are often less understood by providers and less frequently addressed or incorporated within developing systems of care. Women, youth and family members should serve on planning groups at all levels including Ryan White Planning Councils and Consortia, CDC HIV prevention community planning groups, and substance abuse and mental health planning advisory groups. Representatives from Title IV programs should be included, where these programs are present.

Coordination

Planning efforts to implement HIV perinatal recommendations should take place within the larger context of developing and implementing HIV-related systems of care for all affected populations, recognizing that strong linkages are required to address the fragmentation that

Program and System Linkages for Community Participation and Effective Planning

generally characterizes women's health services. Because women enter the health delivery system at many different access points, planning should include a wide variety of institutions and settings. HIV, moreover, affects the entire family system, requiring coordination and integration between multiple systems, programs and agencies that provide services to women (e.g., social services, WIC, reproductive health clinics, Title V programs, substance abuse treatment, etc.).* In order to engage women in care, services need to reflect the reality of women's lives as individuals, caregivers and mothers. Whenever possible, care should be coordinated for women and children, co-locating services and providing care during a single visit.

Outreach and planning efforts should include representatives from the full range of institutions and programs that serve women. While some programs routinely provide health care, they may not provide HIV-related care or counseling and testing services, either on-site or by referral. Lack of inclusion of appropriate agencies and programs in planning and coordination activities can result in poor linkages and lack of awareness of the multiple needs of women and families.

Needs assessments, planning, community education initiatives, and allocation of resources should be coordinated at Federal, State and local levels, with Medicaid and within State plans. Planning should include the full spectrum of care for women and children (e.g., pre/perinatal, pediatric and adult care) with appropriate linkages to related service and support needs. HRSA will work with grantees and related agencies in Federal, State and local government to facilitate coordination across systems and agencies.

PROVIDER TRAINING & TECHNICAL ASSISTANCE

Principles:

- Caregivers need to be sensitive to the high level of distrust and fear that many disenfranchised and racial/ethnic minority persons have toward health care providers and experimental protocols. Culturally appropriate interventions and provider training should be developed to increase trust and utilization of services, to help women with HIV make informed decisions and to promote adherence with treatment recommendations, when treatment is chosen.

*While relevance may vary according to community, this may include: State and local health departments (primary and special health care clinics, as well as publicly funded counseling and testing sites); STD, HIV, maternity, family planning, TB, case management, Title V – maternal and infant care programs, WIC, community health and rural health programs, substance abuse programs; perinatal service system; mental health system, juvenile and adult correctional system; programs funded by the Ryan White CARE Act (Titles I, II, III (b), IV); local social service departments and organizations; local Social Security Administration; community-based health providers, adolescent providers and youth-serving agencies; child/adult protection programs; hospice and home-based health services; local hospitals; provider training programs (e.g., undergraduate professional education, graduate medical education), Area Health Education Centers (AHEC's), legal services (e.g. legal aid); voluntary agencies (e.g. Red Cross, PTAs); housing programs, homeless shelters and health care for the homeless programs; community advocacy groups, churches and schools.

PROVIDER TRAINING NEEDS

Management of HIV Disease
ZDV Perinatal Regimen
HIV Counseling and Testing

- **Communication skills**
- **Non-coercive counseling and informed decision making**
- **Cultural sensitivity and values clarification**
- **Adolescent care and support needs**
- **Social issues, including victimization and domestic violence**
- **Resource and support needs of women and families**

- Health care workers should receive training on prevention intervention strategies, diagnosis and management of HIV disease in women and adolescents, and HIV counseling and testing for women. Content should include basic explanations/education in clear language; benefits and potential risks of ZDV use during pregnancy; and the importance of referrals for care, support services and long-term care. Training should include experiential, interactive methods to allow providers to expand communication skills and address clients' diverse educational and linguistic needs; sensitize providers to cultural diversity, values regarding childbearing and responses to experimental protocols; explore gender-related issues such as victimization and domestic violence; enhance counseling skills and understanding of non-coercive, informed decision making from the perspective of women with HIV; and increase awareness of the emotional, practical and support needs of women, adolescents and families.

- Training should also be provided for paraprofessionals, peer educators and outreach workers who serve as key information resources within communities.

- Training should include skills in negotiating systems and identifying and addressing barriers to care. These skills are particularly important in low-prevalence areas where services are limited and providers are required to locate referrals and follow-up to ensure that women receive care.

- Provider education should be consistent with appropriate professional roles and expectations and geared to the environment in which care is delivered.

Issues Related to Implementation

Cultural Competence and Sensitivity

Cultural competence involves understanding, respect and sensitivity for the diversity of affected populations. To provide appropriate care and facilitate treatment adherence, providers must be aware of and sensitive to the needs of HIV-affected women and families. This requires training related to specific cultural, social and multi-system needs of women and their families, for all persons providing services and care. It also requires development of care and intervention plans that validate the client's cultural beliefs and practices, and culturally sensitive diagnostic and assessment tools. HRSA is currently supporting development of provider training materials and curricula which will be available in 1996.

In addition to sensitivity to clients' cultural and social diversity, providers should also be responsive to their linguistic and educational needs that directly affect comprehension and ability to make informed decisions. Because literacy levels and linguistic needs vary, educational materials should be provided in appropriate languages, presented in a variety of media. The Public Health Service is currently supporting the development of educational materials in English, Spanish, and Creole French which will be available in print format in January 1996; audio and video formats will be available later.

PROGRAM CHECKLIST

Enhancing Capacity to Provide Care for Adolescents

- ❑ **Target outreach materials and strategies to encourage adolescents to use services and to identify health and information needs**
- ❑ **Identify staff who are interested and knowledgeable about adolescents and encourage additional training and continuing education, as needed**
- ❑ **Clarify existing confidentiality and adolescent right to care laws, and develop appropriate policies for clinic staff**
- ❑ **Develop linkages with other programs serving adolescents (e.g., school-based clinics, teen pregnancy programs, youth-serving agencies)**
- ❑ **Develop referral linkages with educational/vocational programs, mental health and specialty care**

Providing effective services to adolescents requires additional sensitivity

and efforts, including heightened awareness of their risk for HIV infection and an understanding of their developmental and support needs. Educational materials, client/provider communication, and training materials should be adapted to reflect adolescent perspectives and comprehension levels; peer-education strategies are particularly effective in reaching this population. Programs can enhance capacity to serve adolescents and families by targeting outreach activities, clarifying confidentiality laws and developing appropriate policies for adolescent care, and developing linkages with youth-serving agencies and appropriate referral resources.

Client Education and Counseling

Providers play a key role in providing basic educational information on perinatal HIV recommendations to women and families. Enabling women with HIV to make informed choices is a critical component in implementing these recommendations. Informed decisions are based on access to accurate information, presented clearly in culturally, linguistically and age-appropriate language. Many women lack in-depth medical knowledge to assist in decision-making, including basic information about HIV disease. Moreover, many women learn their HIV status during pregnancy and thus may have limited time to make key decisions that affect their infants and themselves; the compelling desire to protect their infant further complicates their choices.

COUNSELING CONTENT - CLIENT EDUCATION

- Basic information on HIV disease
- Women's health and immune status
- ACTG 076 study design: three intervention points
- Results and limitations of study
- Benefits and potential risks, including potential for long-term effects
- Rationale and procedures for long-term follow-up

Before describing available options including the perinatal regimen, providers should present the basic facts about ACTG 076 in clear, understandable language, including benefits, potential risks and limitations of the study, discussed in the context of the woman's health and immunological status and stage of pregnancy. Information should include what is known and not known regarding ZDV use during pregnancy, including the potential for long-term adverse effects for the woman and her infant. Several counseling sessions may be needed to enable women to carefully consider their options. Providers can encourage active discussion by offering educational materials for women to review at home, prior to follow-up counseling sessions. Asking questions to ensure that clients understand key issues can facilitate informed decision-making.

Availability of Education and Training

Providing the ZDV perinatal regimen to women who choose this option involves extensive training and technical assistance (TA) for providers, programs and care delivery systems. HIV/AIDS education is available through HRSA's National AIDS Education and Training Centers (AETC) and Ryan White Programs, CDC's STD Prevention Centers, health professions schools, professional associations, and other agencies such as the Red Cross. To ensure the appropriate availability of training and technical assistance, collaboration is required between all entities — Federal, State and local government, professional associations, health professions schools, community groups and private organizations. Women with HIV should play an integral role in developing curricula, participating on multi-disciplinary training teams and providing peer support to other women with HIV.

HRSA will distribute provider and consumer educational materials to all grantees when final versions are available.* In addition, each AETC is required to develop a regional plan for training providers and disseminating information to implement this advisory. Each AETC is establishing a pediatric HIV liaison to coordinate training activities with Title IV programs and providers within the region. (For information on the National AETC Program and ongoing activities, see Resource Information, page 20.)

*Projected to be available in 1996

Technical Assistance

Implementing this regimen, which requires coordination between multiple systems and providers, will increase program needs for technical assistance. These needs range from client-level interventions (such as helping programs and providers understand and manage cultural conflict) to enhancing administrative or management systems (such as developing systems to ensure transferability of medical records or providing training on continuous quality improvement). Resources to initiate broad-based provider training and technical assistance should be sought and allocated to training programs best able to provide education and training on perinatal ZDV management.

Each HRSA Bureau will use a variety of mechanisms to assist grantees in implementing this advisory. These include special sessions during annual program meetings, identifying TA needs during site visits and ongoing monitoring, targeted needs assessments and evaluation activities and providing materials, curricula and protocols. Through the Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission (WIN) program funded in ten sites, the Maternal and Child Health Bureau will provide technical assistance as a follow-up to specific training for physicians, nurses, social workers, psychologists and peer mentors.

HIV COUNSELING AND TESTING/ INFORMED DECISION-MAKING

Principles:

- All settings that provide care to pregnant women and women considering pregnancy should provide routine HIV counseling and voluntary testing on-site or by referral. All pregnant women who have not been tested should be counseled on the benefits of knowing their HIV status (e.g., earlier access to care, PCP prophylaxis for their infants[8]). Whenever possible, however, women should learn their HIV status prior to becoming pregnant. Programs that do not provide HIV testing on-site should provide counseling on the importance of HIV testing and make arrangements for clients who wish to be tested to do so at an appropriate facility.
- HIV testing should be voluntary and should include specific informed consent. Mandatory HIV testing has not been justified. Except for blinded HIV seroprevalence studies, HIV testing without informed consent is unethical.
- HIV counseling and voluntary testing should be made available to women, and men, in all primary care settings and through collaboration with HIV counseling and testing programs.
- Follow-up care for all people with HIV should be provided at HIV counseling and testing sites or by referral. Primary care programs should establish close linkages with HIV counseling and testing sites to ensure optimal follow-up care.

COUNSELING CONTENT - HIV TESTING

- **Rationale for knowing HIV status:**
  - **assistance in making reproductive decisions**
  - **appropriate medical care for woman and infant**
- **Risk reduction information:**
  - **reduce number of partners**
  - **avoid unprotected sex with HIV-infected partners**
  - **use condoms during intercourse**
  - **avoid sharing needles**
- **Risk of HIV transmission to infant:**
  - **15-30% of infants born to mothers with HIV are infected through perinatal transmission if there is no preventive intervention**
- **Availability of ZDV perinatal regimen to reduce maternal-infant transmission of HIV**

- All pregnant women with HIV should receive information on the benefits and potential risks of ZDV use during pregnancy to enable them to make fully informed choices. Information should be provided in clear, culturally, linguistically, and age-appropriate language. Women should be clearly informed that they will continue to receive ongoing care, whether or not they choose to take ZDV. Programs should ensure that women receive appropriate counseling and give informed consent on use of ZDV to reduce perinatal HIV (see Appendix D).

Goals of HIV Counseling and Testing

When first introduced in 1985, the HIV test was used to screen donated blood to protect the nation's blood supply. As it became a widely used diagnostic tool to determine HIV infection status and assess potential treatment needs, testing coupled with counseling became a standard of care. The goals of HIV counseling and testing were redefined to: 1) help people learn their HIV status; 2) facilitate risk-reducing behavioral change; 3) provide access and referrals to follow-up care and services; and 4) provide access and referrals for partners.

Meeting these goals is an ongoing challenge for HIV prevention and early intervention programs. Provider training in HIV counseling and testing has been insufficient and the quality of HIV counseling and testing services varies widely. Although a follow-up visit is required to obtain test results, in some settings, such as STD clinics, less than half of persons tested consistently return for their results.[9] Return rates are substantially higher when trained providers offer testing to clients who consent to testing and agree to return for results[10]. When testing is offered by trained providers women trust, more than 9 out of 10 women agree to be tested.

HIV counseling and testing has not been well integrated into most primary care services or other settings where women receive care. As a result, many women with HIV are not aware of their HIV status and are not tested until they become symptomatic or until their infants are found to be infected.

Risk Assessment & Perceptions of Risk

Previously, HIV counseling and testing strategies targeted persons with self-identified high risk behaviors or who had partners with identified high risk behaviors. Such strategies, however, depend on accurate risk assessments carried out by trained providers and by accurate self-assessment of potential risk factors by clients. Using targeted risk assessment to identify women at risk for infection does not identify more than half of all seropositive women. Many women do not know that they or their partners are infected and do not consider unprotected sex to be a risk behavior. Outreach efforts and services should be targeted to all women, not just those perceived by providers as being "high risk," especially in high seroprevalence areas and settings. PHS guidelines for HIV counseling and voluntary testing of pregnant women recommend that all pregnant women receive counseling on the importance of HIV testing.[1]

Linkages and Referrals for Services and Care

Inadequate linkages between counseling and testing programs and HIV-related services have resulted in lack of appropriate referrals, poor follow-up and inadequate care. Referrals for follow-up services and care should be provided for all persons with HIV; services should be provided on-site or by referral to designated facilities.

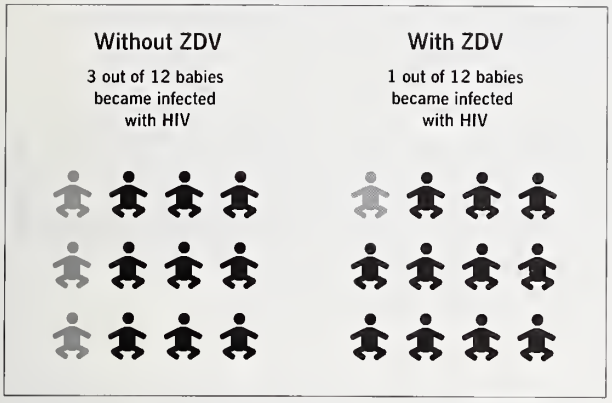
INFORMED DECISION-MAKING

- Use clear, understandable language
- Provide non-coercive counseling
- Clearly state that decision will not jeopardize ongoing care
- Empower women to make an informed decision
- Include family members, partners, confidants
- Allow sufficient time to fully discuss concerns
- Address linguistic and literacy needs
- Provide age-appropriate discussion for adolescents
- Document counseling and decision on written, signed consent form

Programs should collaborate to make optimal use of available resources. For example, Ryan White funds can be used to provide transportation services, including taxi vouchers, to ensure that clients have access to counseling and testing and follow-up care. Maternal and child health programs, family planning clinics and other programs serving women should collaborate with Ryan White programs and counseling and testing sites to incorporate the needs of women into local and regional planning efforts.*

*Ryan White grantees are asked to describe such planning in their funding application

Results of ACTG 076



Counseling for Informed Decision-Making

Deciding to take an HIV test or to seek related treatment are major steps that require access to accurate information and culturally relevant counseling from knowledgeable and sensitive providers. Women must fully understand the results of ACTG 076 to make informed choices. The decision to use ZDV during pregnancy should ultimately be made by the woman without coercion, with a clear understanding that her decision will not jeopardize ongoing services and care.

Counseling should be provided with the goal of informing and empowering women to make their own decisions. ACTG 076 is a complicated study; women may need several counseling sessions, involving family members, partners, friends and others, to make fully informed decisions. They need time to review HIV test results and medical findings, ask questions and discuss their concerns. Adolescents will need age-appropriate discussions.

In addition to discussing benefits, providers should ensure that women clearly understand the study's limitations. For example, women should be informed that while they may follow the regimen, some infants will still become infected: ZDV reduces risk of perinatal HIV transmission — it does not completely prevent transmission in all infants. Inaccurate description of the impact of ZDV may influence a woman's decision by giving a misleading impression that ZDV will prevent transmission of HIV in all infants.

Consent

After a woman has completed counseling and has received information on all aspects of the regimen, counseling should be documented on a written, signed consent form (see Appendix D). The form should specify that she has received basic information about the ZDV perinatal regimen and fully understands her options. The form should provide basic information about the regimen, including benefits and potential risks in clear, understandable language, appropriate to the educational level and linguistic needs of the client. A model consent form is included as Appendix D, which may be used or modified as needed for use in HRSA-funded programs. Additional materials will be provided when HRSA-sponsored consumer and provider educational materials are distributed.*

COMPREHENSIVE CLINICAL CARE & SUPPORT SERVICE NEEDS DURING PRENATAL/PERINATAL PERIOD & POST-TREATMENT FOLLOW-UP

Principles:

- Providers should make ZDV available to women (and their infants) who choose this option, either on-site or by referral. ZDV protocols are complicated; advanced planning and strong linkages are needed to coordinate services among primary care, obstetric, hospital/delivery and pediatric health professionals. For example, appropriate doses of ZDV should be available at all sites where women and infants routinely receive pre-, perinatal and postnatal care.
- All women and infants receiving the ZDV regimen should receive long-term follow-up care. Providers should document infection status and long-term clinical outcomes for both mothers and infants, observing all laws, regulations and provisions that safeguard the confidentiality of medical records.

*Projected to be available in 1996

- Access to a full range of support services and referrals to specialty and subspecialty care should be coordinated at the primary care site or through a lead agency or coordinating agency (when case management or clinical coordination is not available on-site). Whenever possible, medical and core support services should be co-located; this includes counseling and testing, mental health services, substance abuse treatment and child care/respite care.
- Care for pregnant women with HIV should be initiated as early as possible from any point in the system where women access health or related services.
- Agencies should develop written policies and procedures for ZDV management of pregnant women. These should include existing confidentiality provisions, patient's rights, quality assurance and quality improvement standards.*
- Outreach and peer support services should be considered an integral component of comprehensive care; such services enhance continuity of care and increase treatment adherence.

Issues Related to Implementation

Comprehensive Care

The ZDV perinatal regimen, administered within a comprehensive care system, should be considered a standard of care for pregnant women with HIV; however, the decision to follow the regimen will be ultimately made by the woman. Mainstream care settings provide the most likely opportunities for identifying women with HIV before conception and during early stages of pregnancy, to allow optimal treatment and maximum options. Providing the regimen within this broad context of health care services requires extensive coordination and linkages between multiple service systems.

Comprehensive care and support services for women with HIV — from pre-natal through post-treatment care — include a full range of medical, support services and basic life needs provided in a supportive, client-centered environment. Key needs for managing care include: provision of care by supportive individuals or a multidisciplinary team, access to peer and professional support (particularly during the period immediately following diagnosis), case management, comprehensive assessment of the woman's needs, comprehensive client education providing options for care, primary care and a plan for managing the birth process. (See implementation diagram on the following page.)

COMPONENTS OF COMPREHENSIVE CARE

HEALTH CARE

Primary and specialty care (including adolescent care), HIV-related care and pharmaceuticals, preventive care, emergency and acute care, linkage to pediatric care, access to clinical trials, dental care, nutritional services, substance abuse services, counseling and mental health services, health education and partner related services

SUPPORT SERVICES

Case management, social services, family support services, child and respite care, youth and school-based services, health education, entitlements counseling, peer support and outreach. (These services are needed to help women access and remain in care. Protocols that involve frequent visits to primary care providers call for informed clients who are active care partners.)

BASIC LIFE NEEDS

Housing assistance, food, transportation, and interpreter services help meet basic survival needs

LEGAL AND ADVOCACY SERVICES

Services to help manage discrimination or assist with preparing wills, adoption or permanency planning. (These services may be particularly important for homeless women and those who inject or have injected illegal drugs.)

Need for Follow-up

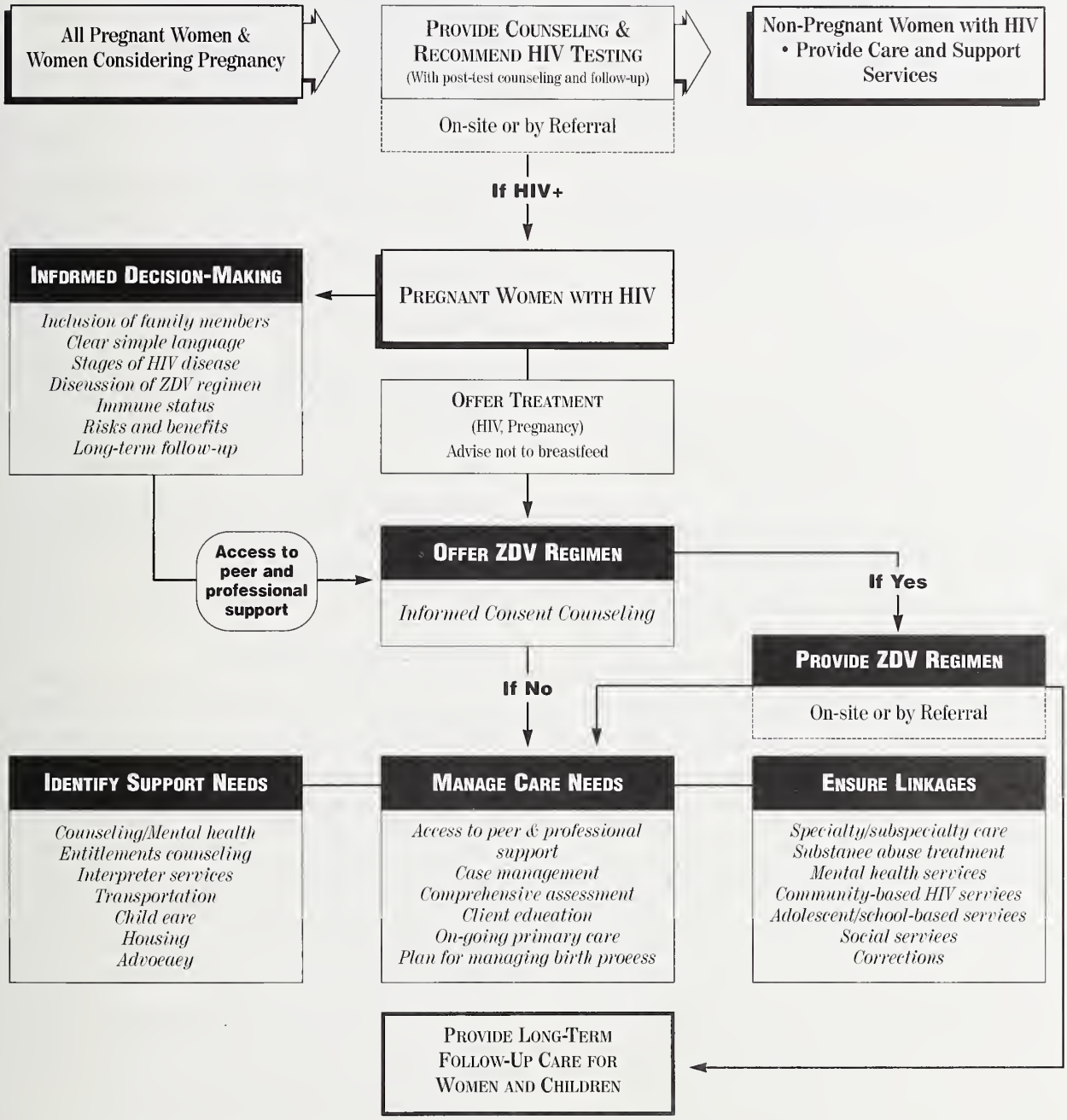
ACTG 076 studied only short-term effects of the ZDV perinatal regimen. Eventually other studies (see page 17) will provide information on long-term effects; until then, long-term follow-up care of mothers and infants in primary care settings is essential to monitor for potential negative health outcomes.

Follow-up may help:

- provide information on possible adverse reactions and outcomes to allow for early detection and treatment, should these occur;

*For example, see N.Y. State Department of Health, AIDS Institute, Clinical Guidelines for the Use of Zidovudine Therapy in Pregnancy to Reduce Perinatal Transmission of HIV, October 1994, for model policy and procedures. This document is available from the HRSA AIDS Program Office.

Implementation of ZDV Perinatal Therapy in HRSA-Funded Programs



- provide information on current gaps regarding the effects and outcomes of an incomplete regimen (e.g., when women receive treatment later during pregnancy or delivery or when only the infant receives ZDV after delivery);
- generate mechanisms to accurately report health outcomes for women and uninfected and infected infants;
- provide information to help define service and care needs for women and children who receive the regimen.

Encouraging Follow-Up

Long-term follow-up may occur in a variety of settings, including medical centers, HIV specialty programs, primary care clinics or private practitioners' offices. Participation is voluntary. Women and children are more likely to remain in care and participate in follow-up care when: 1) the care setting is welcoming; 2) providers are supportive and accepting of womens' needs and are flexible when appointments are missed or women return infrequently; 3) women and families clearly understand the importance of follow-up (i.e., both the client's and provider's expectations are clearly defined); 4) providers share findings after each visit, reinforcing the value of a consistent care team and long-term follow-up; 5) providers stay in touch with families between visits (e.g., sending birthday cards or notes) particularly if families are seen infrequently, and outreach workers routinely follow-up when visits are missed; 6) support services (e.g., child care, transportation, food vouchers) are directly linked to care, enabling women and children to keep appointments; 7) contact information is updated during each visit, including telephone, address and information on extended family members and close friends; and 8) mothers receive psychosocial support for child custody or permanency planning, including periodic discussion of how follow-up care will be maintained after her death.

Suggested Protocol for Long-Term Follow-up

Primary care programs should develop a follow-up protocol for women and children who received the regimen (see protocol on page 19). Follow-up monitoring should be integrated into routine and regular care. Providers should document clinical and laboratory results for mothers and children, maintained as part of the client's medical record, until standardized forms are developed to facilitate reporting and follow families to other care settings. Confidentiality of both mother and child should be protected; in many cases, women do not disclose their HIV status or their child's to others, even to family members.

Adverse events should be reported through established mechanisms such as FDA's MedWatch, Western Stream and the Antiretroviral Pregnancy Registry, or coordinated through special studies for uniform long-term data collection conducted by NIH, CDC and HRSA (e.g., Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission).

Program Implementation

Implementing these recommendations involves planning and coordination at all levels and across multiple service delivery systems. Close collaboration with women with HIV, affected communities, local agencies and providers is essential. Clearly, implementing the regimen involves commitment of staff, time and financial resources. At a more basic level, moreover, implementation compels providers, program managers and public health officials to more closely integrate prevention and primary care services, at both planning and service delivery levels. Above all, the need to carefully weigh the benefits and potential risks of taking the regimen requires careful consultation between women and their providers.

HRSA will work closely with grantees to identify technical assistance and planning needs and to incorporate feedback and share effective strategies as implementation needs evolve.

Recommended Protocol for Long-term Follow-up of Women and Children

Follow-up care should be provided for women and infants who have received the ZDV perinatal regimen. This should include the following guidelines, at a minimum, as well as any additional visits or assessments that are medically indicated.

WOMEN

- Women should receive ongoing personal medical care appropriate to their health status, and not limited to HIV-related care.
- Routine visits should occur at 6,12, 18, 24 and 36 months, post-partum, and yearly thereafter.
- Each visit should include history and physical, pap smear, routine chemistry and hematology bloodwork and CD4+ T-cell levels.
- Indicated HIV care (STD, TB and OI screening, PCP prophylaxis).

INFANTS

- Routine visits for all infants should occur at 2 and 6 weeks of age (while receiving zidovudine), and then every 3 months until infection status is determined. HIV culture and PCR should be used to establish infection status.
- Provide preventive medical care including PCP prophylaxis[8] and immunizations according to current guidelines and as medically indicated.
- When HIV status is determined (6 months - 2 years), infected infants/children should be seen every 3 months with additional visits or assessments as medically indicated. Each visit should include a history and physical, routine hematology and chemistry tests, evaluation of immune function and office-based neurodevelopmental assessment including both mental or cognitive and motor function (e.g., Denver developmental test). The older child should also be assessed for school performance, peer relations and support needs.
- Uninfected infants/children should be seen as appropriate for routine health care and immunization (e.g., every 3 months through 24 months of age) then yearly until age 21, to monitor for long-term effects of zidovudine exposure. Visits should include a history and physical, routine hematology and chemistry tests, office-based neurodevelopmental assessment including both mental or cognitive and motor function (e.g., Denver developmental test), and assessment of school performance, peer relations and support needs (for older children).
- Give special consideration during each visit to assessing the mother's health status and her plans for custodial care if she becomes unable to care for her child. Incorporate continuity of the child's health care into this plan.

  Share findings with the mother and family after the visit.

RESOURCE INFORMATION

AIDS Clinical Trials Information Service: 1-800-TRIALS-A, TTY/TDD 1-800-243-7012

AIDS Program Office, Health Resources and Services Administration: 301-443-4588

Antiretroviral Pregnancy Registry: 1-800-722-9292, ext. 58465

HRSA/AIDS ETC National HIV Telephone Consultation Service (for health care providers): 1-800-933-3413

HIV/AIDS Treatment Information Service 1-800-HIV-0440

National Institute of Allergy and Infectious Diseases (NIAID), NIH
NIAID Office of Communications: 301-402-1663

National Institute of Child Health and Human Development (NICHD), NIH
NICHD Office of Communications: 301-496-5133

National HIV/AIDS Education and Training Centers (AETC) Program, HRSA: 301-443-6364

National AIDS Information Clearinghouse (NAIC), CDC: 1-800-458-5231

Also available from NAIC:

Early HIV Infection, Clinical Practice Guidelines, Agency for Health Care Policy and Research pub. 94-0572

Pregnancy and HIV: Is AZT the Right Choice for You and Your Baby?, Agency for Health Care Policy and Research pub. 96-0007

National Pediatric and Family HIV/AIDS Resource Center, HRSA: 1-800-362-0071

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APPENDIX A

PHS RECOMMENDATIONS FOR HIV COUNSELING AND VOLUNTARY TESTING OF PREGNANT WOMEN[1]

HIV Counseling and Voluntary Testing of Pregnant Women and Their Infants

- Health care providers should ensure that all pregnant women are counseled and encouraged to be tested for HIV infection to allow women to know their infection status both for their own health and to reduce the risk for perinatal HIV transmission. Pretest HIV counseling of pregnant women should be in accordance with previous guidelines for HIV counseling.[11,12] Such counseling should include information regarding the risk for HIV infection associated with sexual activity and injecting-drug use, the risk for transmission to the woman's infant if she is infected, and the availability of therapy to reduce this risk. HIV counseling, including any written materials, should be linguistically, culturally, educationally, and age appropriate for individual patients.

- HIV testing of pregnant women and their infants should be voluntary. Consent for testing should be obtained in accordance with prevailing legal requirements. Women who test positive for HIV or who refuse testing should not be a) denied prenatal or other health-care services, b) reported to child protective service agencies because of refusal to be tested or because of their HIV status, or c) discriminated against in any other way.

- Health care providers should counsel and offer HIV testing to women as early in pregnancy as possible so that informed and timely therapeutic and reproductive decisions can be made. Specific strategies and resources will be needed to communicate with women who may not obtain prenatal care because of homelessness, incarceration, undocumented citizenship status, drug or alcohol abuse, or other reasons.

- Uninfected pregnant women who continue to practice high-risk behaviors (e.g., injecting drug-use and unprotected sexual contact with an HIV-infected or high-risk partner) should be encouraged to avoid further exposure to HIV and to be retested for HIV in the third trimester of pregnancy.

- The prevalence of HIV infection may be higher in women who have not received prenatal care. These women should be assessed promptly for HIV infection. Such an assessment should include information regarding prior HIV testing, test results, and risk history. For women who are first identified as being HIV infected during labor and delivery, health care providers should consider offering intrapartum and neonatal ZDV according to published recommendations.[2] For women whose HIV infection status has not been determined, HIV counseling should be provided and HIV testing offered as soon as the mother's medical condition permits. However, involuntary HIV testing should never be substituted for counseling and voluntary testing.

- Some HIV-infected women do not receive prenatal care, choose not to be tested for HIV, or do not retain custody of their children. If a woman has not been tested for HIV, she should be informed of the benefits to her child's health of knowing her child's infection status and should be encouraged to allow the child to be tested. Counselors should ensure that the mother provides consent with the understanding that a positive HIV test for her child is indicative of infection in herself. For infants whose HIV status is unknown and who are in foster care, the person legally authorized to provide consent should be encouraged to allow the infant to be tested (with the consent of the biologic mother,when possible) in accordance with the policies of the organization legally responsible for the child and with prevailing legal requirements for HIV testing.

- Pregnant women should be provided access to other HIV prevention and treatment services (e.g., drug treatment and partner-notification services) as needed.

Recommendations for HIV-Infected Pregnant Women

- HIV-infected pregnant women should receive counseling as previously recommended.[4] Post-test HIV counseling should include an explanation of the clinical implications of a positive HIV antibody test result and the need for, benefit of, and means of access to HIV-related medical and other early intervention services. Such counseling should also include a discussion of the interaction between pregnancy and HIV infection, the risk of HIV perinatal HIV transmission and ways to reduce this risk, and the prognosis for infants who become infected.

- HIV-infected pregnant women should be evaluated according to published recommendations to assess their need for antiretroviral therapy, antimicrobial prophylaxis, and treatment of other conditions. Although medical management of HIV infection is essentially the same for pregnant and nonpregnant women, recommendations for treating a patient who has tuberculosis have been modified for pregnant women because of potential teratogenic effects of specific medications (e.g., streptomycin or pyrazinamide). HIV-infected pregnant women should be evaluated for their need for psychological and social services.

- HIV-infected pregnant women should be provided information concerning ZDV therapy to reduce the risk for perinatal HIV transmission. This information should address the potential benefit and short-term safety of ZDV and the uncertainties regarding a) long-term risks of such therapy and b) effectiveness in women who have different clinical characteristics (e.g., CD4+ T-lymphocyte count and previous ZDV use) than women who participated in the trial. HIV-infected pregnant women should not be coerced into making decisions about ZDV therapy. These decisions should be made after consideration of both the benefits and potential risks of the regimen to the woman and her child. Therapy should be offered according to the appropriate regimen in published recommendations.[5] A woman's decision not to accept treatment should not result in punitive action or denial of care.

- HIV-infected pregnant women should receive information about all reproductive options. Reproductive counseling should be nondirective. Health care providers should be aware of the complex issues HIV-infected women must consider when making decisions about their reproductive options and should be supportive of any decision.

- To reduce the risk of HIV transmission to their infants, HIV-infected women should be advised against breast feeding. Support services should be provided when necessary for use of appropriate breast milk substitutes.

- To optimize medical management, positive and negative HIV test results should be available to a woman's health care provider and included on both her and her infant's confidential medical records. After obtaining consent, maternal health care providers should notify the pediatric care providers of the impending birth of an HIV-exposed child, any anticipated complications, and whether ZDV should be administered after birth. If HIV is first diagnosed in the child, the child's health care providers should discuss the implication of the child's diagnosis for the woman's health and assist the mother in obtaining care for herself. Providers are encouraged to build supportive health care relationships that can facilitate the discussion of pertinent health information. Confidential HIV-related information should be disclosed or shared only in accordance with prevailing legal requirements.

- Counseling for HIV-infected pregnant women should include an assessment of the potential for negative effects resulting from HIV infection (e.g., discrimination, domestic violence, and psychological difficulties). For women who anticipate or experience such effects, counseling should also include a) information on how to minimize these poten-

tial consequences, b) assistance in identifying supportive persons within their own social network, and c) referral for appropriate psychological, social, and legal services. In addition, HIV-infected women should be informed that discrimination based on HIV status or AIDS regarding matters such as housing, employment, State programs, and public accommodations (including physicians' offices and hospitals) is illegal.

- HIV-infected women should be encouraged to obtain HIV testing for any of their children born after they became infected or, if they do not know when they became infected, for children born after 1977. Older children (i.e., children >12 years of age) should be tested with informed consent of the parent and assent of the child. Women should be informed that the lack of signs and symptoms suggestive of HIV infection in older children may not indicate lack of HIV infection; some perinatally infected children can remain asymptomatic for several years.

Recommendations for Follow-up of Infected Women and Perinatally Exposed Children

- Following pregnancy, HIV-infected women should be provided ongoing HIV-related medical care, including immune-function monitoring, antiretroviral therapy, and prophylaxis for and treatment of opportunistic infections and other HIV-related conditions. HIV-infected women should receive gynecologic care, including regular Pap smears, reproductive counseling, information on how to prevent sexual transmission of HIV, and treatment of gynecologic conditions according to published recommendations.

- HIV-infected women (or the guardians of their children) should be informed of the importance of follow-up for their children. These children should receive follow-up care to determine their infection status, to initiate prophylactic therapy to prevent PCP, and, if infected, to determine the need for antiretroviral and other prophylactic therapy and to monitor disorders in growth and development, which often occur before 24 months of age. HIV-infected children and other children living in households with HIV-infected persons should be vaccinated according to published recommendations for altered schedules.

- Because the identification of an HIV-infected mother also identifies a family that needs or will need medical and social services as her disease progresses, health care providers should ensure that referrals to these services focus on the needs of the entire family.

APPENDIX B

PHS RECOMMENDATIONS ON THE USE OF ZDV TO REDUCE PERINATAL TRANSMISSION OF HIV[2]

These recommendations should be followed by all providers implementing the ZDV perinatal regimen in HRSA-funded programs:

I. Pregnant HIV-infected women with CD4+ T-lymphocyte counts ≥ 200 µL who are at 14-34 weeks of gestation and who have no clinical indications for ZDV and no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:

The health care provider should recommend the full ACTG Protocol 076 regimen to all HIV-infected pregnant women in this category. This recommendation should be presented to the pregnant woman in the context of a risk-benefit discussion: a reduced risk of transmission can be expected, but the long-term adverse consequences of the regimen are not known. The decision about this regimen should be made by the woman after discussion with her health care provider.

II. Pregnant HIV-infected women who are at >34 weeks of gestation, who have no history of extensive (>6 months) prior antiretroviral therapy, and who do not require ZDV for their own health.

Recommendation:

The health care provider should recommend the full ACTG Protocol 076 regimen in the context of a risk-benefit discussion with the pregnant woman. The woman should be informed that ZDV therapy may be less effective than that observed in ACTG Protocol 076, because the regimen is being initiated late in the third trimester.

III. Pregnant HIV-infected women with CD4+ T-lymphocyte counts <200 µL who are at 14-34 weeks of gestation, who have no other clinical indications for ZDV, and who have no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:

The health care provider should recommend initiation of antenatal ZDV therapy to the woman for her own health benefit. The intrapartum and neonatal components of the ACTG Protocol 076 regimen should be recommended until further information becomes available. This recommendation should be presented in the context of a risk-benefit discussion with the pregnant woman.

IV. Pregnant HIV-infected women who have a history of extensive (>6 months) ZDV therapy and/or other antiretroviral therapy before pregnancy.

Recommendation:

Because data are insufficient to extrapolate the potential efficacy of the ACTG Protocol 076 regimen for this population of women, the health care provider should consider recommending the ACTG Protocol 076 regimen on a case-by-case basis after a discussion of the risk and benefits with the pregnant woman. Issues to be discussed include

her clinical and immunologic stability on ZDV therapy, the likelihood that she is infected with a ZDV-resistant HIV strain, and, if relevant, the reasons for her current use of an alternative antiretroviral agent (e.g., lack of response to or intolerance of ZDV therapy.) Consultation with experts in HIV infection may be warranted. The health care provider should make the ACTG Protocol 076 regimen available to the woman, although its effectiveness may vary depending on her clinical status.

V. Pregnant HIV-infected women who have not received antepartum antiretroviral therapy and who are in labor.

Recommendation:

For women with HIV infection who are in labor and who have not received the antepartum component of the ACTG Protocol 076 regimen (either because of lack of prenatal care or because they did not wish to receive antepartum therapy), the health care provider should discuss the benefits and potential risks of the intrapartum and neonatal components of the ACTG Protocol 076 regimen and offer ZDV therapy when the clinical situation permits.

VI. Infants who are born to HIV-infected women who have received no intrapartum ZDV therapy.

Recommendation:

If the clinical situation permits and if ZDV therapy can be initiated within 24 hours of birth, the health care provider should offer the ACTG Protocol 076 postpartum component of 6 weeks of neonatal ZDV therapy for the infant in the context of a risk-benefit discussion with the mother. Data from animal prophylaxis studies indicate that, if ZDV is administered, therapy should be initiated as soon as possible (within hours) after delivery. If therapy cannot begin until the infant is >24 hours of age and the mother did not receive therapy during labor, no data support offering therapy to the infant.

APPENDIX C

Agency and Bureau Plan for Coordinating Implementation of ZDV Perinatal Therapy in HRSA-Funded Programs

HRSA
OFFICE OF THE ADMINISTRATOR

AIDS PROGRAM OFFICE (APO)

- Sponsor constituency meetings to identify issues and strategies for implementing ZDV perinatal regimen
- Send advisory letters from HRSA Administrator and Program Advisory based on constituency meetings to all grantees
- Collaborate with Bureaus to coordinate implementation activities including consumer education and provider training
- Collaborate with State health departments and other PHS agencies
- Sponsor special evaluation projects with MCHB

BUREAU OF PRIMARY HEALTH CARE (BPHC)

- BPHC Implementation Plan
- Title II(b) Application Guidance to require plan for expanded counseling and testing for women implementation of ZDV perinatal therapy and progress measures
- Technical Assistance to Grantees
- Special sessions at annual program meetings
- Collaborate with other Bureaus to share TA and implementation strategies

Ryan White Title II(b)

BUREAU OF HEALTH RESOURCES DEVELOPMENT (BHRD)

- BHRD Implementation Plan
- Title I & II Application Guidance to require implementation plan and progress measures
- Technical Assistance to Grantees
- Special sessions at annual program meetings
- Incorporate assessment of related TA needs into ongoing site visits and monitoring activities
- Collaborate with NASTAD on needs assessments strategies and implementation models
- Incorporate 3 SPNS projects (funded FY 94) into the WIN* program and evaluate outcome

Ryan White Titles I & II SPNS

MATERNAL & CHILD HEALTH BUREAU (MCHB)

- MCHB Implementation Plan
- Title V Application Guidance to require implementation of counseling and testing and treatment of pregnant women
- Technical Assistance to Grantees
- Implement WIN* Cooperative Agreement with Title IV Grantees
- Sponsor national survey of State health departments to develop a guidance for counseling and testing and care
- Support development of consumer education materials provider education and training curricula (with BHPr)

Ryan White Title IV

BUREAU OF HEALTH PROFESSIONS (BHPr)

- BHPr Implementation Plan
- AETC Application Guidance to require regional plan for information dissemination and provider training comprehensive input from PWAs
- Special sessions at annual program meetings
- Training through HIV Clinical Conference Call Series and National Telephone Consultation Service
- Special regional and local conferences
- In-depth training (clerkships) in pediatric HIV care including ZDV perinatal therapy
- Develop and coordinate provider training materials and curricula
- Collaborate with other Ryan White and HRSA programs and WIN*

National AIDS Education & Training Centers Program (AETC)

* *Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission (WIN)*

APPENDIX D

This form has been developed as a draft for use by HRSA-funded programs. It is based on informed consent forms used by programs implementing the ZDV perinatal regimen. Providers are encouraged to use or modify this form as needed to ensure that appropriate counseling is provided and to help avoid potential legal problems that may occur if counseling is not adequately documented.

Following counseling session(s), providers should ask women to read and sign such a form to indicate that they have received specific information about the regimen, have had an opportunity to discuss their concerns, and have made a decision about whether or not to accept the regimen. When women are unable to read the form, providers should read it to them, clearly reviewing the information it contains to ensure that women are able to make fully informed decisions.

Model Form
To Document Counseling and Consent for Administration of the ZDV Perinatal Regimen

I have been counseled by my care providers on use of ZDV (AZT) to reduce the chance of passing HIV from mother-to-infant. If my CD4+T-cell count drops below 500 or if I develop symptoms of HIV disease, my provider may suggest that I take ZDV for my own well-being (not only to reduce the chance of passing HIV to my infant).

My care provider has discussed the following information with me in language I can understand:

- ZDV *regimen* to reduce the chance of passing HIV from mother to infant (*Regimen* means how ZDV is given to women and infants. Women take ZDV during pregnancy, labor and delivery and infants take it during the first 6 weeks of life)
- Benefits and potential risks of the ZDV regimen
- My right to make this decision on my own, without pressure from my health care providers
- My rights (and my infant's rights) to confidentiality
- Need for long-term follow-up care
- Basic information on HIV/AIDS
- Counseling on why I should not breast feed my infant
- My health and immune status

ZDV Regimen: Benefits and Risks

My care provider has explained that women with HIV have about a one out of four chance of passing HIV to their infants. This means that three out of twelve infants born to mothers with HIV will also have HIV. A large study of more than 500 pregnant women showed that ZDV could lower the chance of passing HIV from mothers to infants by two-thirds. In the study (ACTG 076), only one out of twelve infants born to mothers with HIV also had HIV. Other kinds of studies have also shown that ZDV can lower the risk of passing HIV from mothers to infants. My provider has explained these new studies to me as they are completed.

I understand that this is considered to be an important option to reduce the risk of passing HIV from mother to infant. Even though I may decide to take ZDV, my infant may still get infected because ZDV does not completely prevent HIV in all infants. I also understand that no one knows the long-term effects of ZDV on infants (or mothers).

My provider has explained that women in the study (ACTG 076)

- Received early prenatal care
- Did not take ZDV for their own health before the study began
- Started taking ZDV between 14 weeks (3 1/2 months) and 34 weeks (8 1/2 months) of pregnancy
- Had T-cell counts above 200 when the study began, and more than half had T-cell counts above 500.

Most of the women were African-American or Hispanic (79 percent) and their average age was 25. I understand that women in the study received care under the best conditions to reduce the risk of passing HIV to their infants. In other words, they had early prenatal care, knew their HIV status, had higher T-cell counts and took a full course of ZDV (during pregnancy, labor, delivery; infants took it for 6 weeks). My provider has explained that ZDV may not have the same result if my history is different from women in ACTG 076. My provider has also explained other new studies that have reduced HIV in infants and how I compare to women in those studies.

I have received basic information on HIV disease and my provider has explained my T-cell count and stage of HIV disease.

Right to Decide

I understand that I have the right to decide if I want to take ZDV or not. If I choose to take ZDV, I understand that I can change my mind at any time — for myself or my infant. If I do not take ZDV or if I decide to stop taking it, my infant and I will still receive care.

Medical Monitoring

I understand that while I take ZDV, my providers will continue to check my health status. This includes taking a blood test (complete blood count) each month and checking my CD4+T-cell count (key immune system cells) to measure my immune status. If I decide to take ZDV, I understand that I will take it five times a day during pregnancy, during labor and delivery through an IV, and my infant will take it four times a day for 6 weeks.

Short-term Effects

I understand that some people who take ZDV may have short-term side effects that usually go away after they stop taking ZDV. These may include low blood count (anemia), upset stomach, nausea, vomiting, rashes, muscle aches (myalgia), headache, difficulty sleeping (insomnia), numbness or tingling feelings on the skin (paresthesia) and hepatitis in adults and infants. People with HIV who do not take ZDV may also have these symptoms.

Women and children who were in the study did not have serious short-term side effects. Some infants had mild anemia, but this cleared up after they stopped taking ZDV.

Long-term Effects

I understand that the study did not last long enough to know if the ZDV regimen will cause health problems for women and children at a later time. (For example, I understand that some other drugs have later caused birth defects or cancer in children or adults when their mothers took these drugs during pregnancy.) There are two other studies looking at women and infants who were in the ACTG 076 study. But these will not be finished for several years. For this reason, women and children will receive long-term follow-up care to see if serious health problems develop.

Long-term Follow-up

I understand that if I decide to take ZDV, my child and I will be asked to come in for medical check-ups every year until my child reaches age 21. During these visits, providers will check for possible side effects, share information on health status and help with long-term planning for my child's care.

Confidentiality

I understand that my providers must protect my confidentiality and my infant's under State laws. My providers have explained State and local laws about confidentiality of HIV. In some cases they may have to share my HIV status with other persons. If they are required to share my HIV status, they will tell me who else must know my health status and my infant's. I understand that my decision about taking ZDV will not be shared with others unless the law requires them to know.

Decision About Use of ZDV

I have read this form or had it read to me in a language I can understand. I understand what I have read and what my provider has told me about HIV disease and the ZDV regimen. I have discussed this information with my provider and have asked questions about HIV disease and the ZDV regimen. I feel that I have enough information about ZDV and its benefits and risks to make an informed decision.

My provider has recommended that I take the ZDV regimen.

I understand that ZDV may help lower the chance of passing HIV to my infant. I also understand that it may not work as well for me as it did for women in the study (ACTG 076) because some infants still became infected even after their mothers took ZDV. No one has made any promises to me about what to expect from taking ZDV.

I understand that I will still receive ongoing care if I decide not to take ZDV and I have the right to change my mind at any time.

CONSENT

❑ **I CHOOSE** to take the ZDV regimen.

❑ **I CHOOSE** to allow my infant to receive ZDV after he/she is born.

_____

Patient's Signature

_____

Date

_____

Witness's Signature

_____

Date

_____

If Patient is Unable to Sign

_____

Relationship

_____

Date

_____

I have discussed all of the information included in this form with my client and have provided an opportunity for her and her family to ask questions and discuss their concerns.

_____

Health Care Provider

_____

Date

DO NOT CONSENT

❑ **I CHOOSE NOT** to take the ZDV regimen at this time.

_____

Patient's Signature

_____

Date

_____

Witness's Signature

_____

Date

_____

If Patient is Unable to Sign

_____

Relationship

_____

Date

_____

I have discussed all of the information included in this form with my client and have provided an opportunity for her and her family to ask questions and discuss their concerns.

_____

Health Care Provider

_____

Date

U.S. Department of Health & Human Services
Public Health Service
Health Resources & Services Administration